IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

In re Testosterone Replacement Therapy Products Liability Litigation Coordinated Pretrial Proceedings	)	**Case No. 14 C 1748** **MDL No. 2545**
(This document applies to *Martin v. Actavis, Inc.*, Case No. 15 C 4292)	)	

CASE MANAGEMENT ORDER NO. 176
(Memorandum Opinion and Order on Actavis, Inc.'s motion to exclude the testimony of Plaintiff's expert Joshua Sharlin, Ph.D. in *Martin v. Actavis, Inc.*, Case No. 15 C 4292)

MATTHEW F. KENNELLY, District Judge:

In this multidistrict litigation (MDL) proceeding, Plaintiff Brad Martin alleges that he suffered a myocardial infarction (heart attack) as a result of taking Androderm, a prescription testosterone replacement therapy (TRT) drug manufactured or sold by Defendants Actavis, Inc., Actavis Pharma, Inc., and Actavis Laboratories UT, Inc. (collectively, Actavis). In August 2019, Martin informed the Court that he has elected not to settle his claims under the Master Settlement Agreement covering cases involving Actavis. In December 2019, the Court denied Actavis's motion to exclude expert testimony concerning general and specific causation; denied Actavis's motion for summary judgment based on federal preemption; and granted in part and denied in part Actavis's motion for summary judgment on Martin's state law claims. *See In re Testosterone Replacement Therapy Prods. Liability Litig. Coordinated Pretrial Proceedings*, 430 F. Supp. 3d 516 (N.D. Ill. 2019) (CMO 166).

In January 2020, the Court granted Martin's motion to substitute a new expert witness—Dr. Joshua Sharlin—for Dr. Peggy Pence, who had been serving as Martin's

Food and Drug Administration (FDA) regulatory expert, and whose opinions Actavis did not move to exclude. Actavis now moves to exclude a number of opinions that Dr. Sharlin offers. The Court addresses Actavis's motion in this decision.

Background

The Court assumes familiarity with its prior orders in the MDL but discusses them as necessary here.

Dr. Pence has provided expert reports, deposition testimony, and trial testimony for plaintiffs in this MDL whose cases were selected for bellwether trials. Her expertise includes ensuring that prescription drugs are researched, developed, labeled, and marketed in compliance with FDA requirements. In Martin's case, Dr. Pence submitted an expert report and provided deposition testimony. Among other things, she opined that Actavis should have added a cardiovascular (CV) risk warning to the Androderm label by 2007 and that the warning should have been similar to the one that the FDA required Actavis to add in May 2015. She also opined that Actavis marketed Androderm for the treatment of age-related hypogonadism, an off-label use, despite that it knew or should have known about the CV risk and that the safety and efficacy of the off-label use have not been established.

In November 2019, for reasons that are irrelevant here, Dr. Pence told Martin that she could not serve as his FDA regulatory expert at trial. As noted, the Court granted Martin's motion to substitute Dr. Sharlin. Dr. Sharlin then submitted an expert report. He "adopt[ed] Dr. Pence's report, including her conclusions" but explained that he "independently reached [his] own conclusions." Actavis's Mot. to Exclude the Testimony of Pl.'s Expert Joshua Sharlin, Ph.D., Ex. 2 (Sharlin Report) [129-2] ¶ 192.

Like Dr. Pence, Dr. Sharlin opines that Actavis should have added a CV risk warning to the Androderm label before the FDA required it to do so in May 2015. According to Dr. Sharlin, Actavis should have added the warning by 2011. Dr. Sharlin also opines that Actavis promoted Androderm for the treatment of age-related hypogonadism. Actavis challenges these and other opinions under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

Before filing its *Daubert* motion, Actavis moved to strike Dr. Sharlin's expert report. The Court granted the motion in part following a hearing on February 14, 2020. It excluded Dr. Sharlin's opinions about the total number of CV-related events for TRT drugs allegedly extracted from the FDA's adverse event reporting system (FAERS) database using targeted search terms. The Court determined that those opinions went "significantly beyond" what Dr. Pence previously disclosed in her expert report and deposition testimony and that Martin's failure to disclose the opinions was not substantially justified or harmless. Actavis Reply in Supp. of Mot. to Exclude, Ex. 1 (Feb. 14, 2020 Hr'g Tr.) [148-1] at 6:4-7, 7:2-14 (excluding the undisclosed opinions under Federal Rule of Civil Procedure 37(c)(1)). The excluded material, the Court explained, is referenced in "the first two bullet points on page 6 of Actavis' motion to strike." *Id.* at 7:15-17. Those bullet points are reproduced here:

- A purported totaling of so-called "Cardiovascular Related Adverse Events" allegedly extracted from FDA's FAERS (adverse event report) database for the class of TRT products allegedly derived from using 97 MedDRA terms Dr. Ardehali believes represent "CV related events". ([Sharlin Report], pp. 22-25.) This counting of AERs is the lynchpin of various opinions from Dr. Sharlin about alleged regulatory deficiencies by Actavis. (*See* [Sharlin Report] at pp. 4-5, 25-28.)

- The new FAERS counting leads to a stacking of speculation that researchers could have started work earlier and FDA could have

> concluded the studies were inconclusive earlier. (*See* [Sharlin Report] at pp. 4-5, 25-28.)

Actavis Mot. to Strike [108], at 6. The Court denied Actavis's motion to strike in all other respects. Actavis took Dr. Sharlin's deposition in February 2020. In May 2020, Actavis moved to strike changes in the errata sheet attached to the deposition transcript. The Court denied the motion, and neither side has indicated that the contents of the errata sheet are relevant to the present *Daubert* dispute.

Discussion

Federal Rule of Evidence 702 and the principles set forth in *Daubert* govern the admissibility of expert testimony. "In *Daubert*, the Supreme Court interpreted Rule 702 to require the district court to act as an evidentiary gatekeeper, ensuring that an expert's testimony rests on a reliable foundation and is relevant to the task at hand." *Gopalratnam v. Hewlett-Packard Co.*, 877 F.3d 771, 778 (7th Cir. 2017) (internal quotation marks omitted). To this end, the district court must engage in what is essentially a three-step analysis: it must determine whether (1) the expert is qualified; (2) the reasoning or methodology underlying the expert's testimony is reliable; and (3) the testimony is relevant, meaning likely to assist the trier of fact to understand the evidence or to determine a fact in issue. *Id.* at 779 (citing *Myers v. Ill. Cent. R.R. Co.*, 629 F.3d 639, 644 (7th Cir. 2010)). The expert's testimony is admissible only if all three hurdles are cleared.

The district court's role as gatekeeper is meant to ensure that an expert "employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999). In exercising its gatekeeping role, a court does not ask whether the expert "is qualified

in general," but rather whether he is qualified "to answer a specific question." *Gayton v. McCoy*, 593 F.3d 610, 617 (7th Cir. 2010) (quoting *Berry v. City of Detroit*, 25 F.3d 1342, 1351 (6th Cir. 1994)). Further, a court should focus on the expert's "principles and methodology" rather than on his conclusions, *Daubert*, 509 U.S. at 595, or the "factual underpinnings" of those conclusions. *Walker v. Soo Line R.R. Co.*, 208 F.3d 581, 586 (7th Cir. 2000). That said, an opinion must be connected to the existing data by more than an expert's "*ipse dixit.*" *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). An opinion may be inadmissible if there is "too great an analytical gap between the data and the opinion proffered." *Id.* An opinion must also "fit the issue to which the expert is testifying and be tied to the facts of the case." *Owens v. Auxilium Pharm., Inc.*, 895 F.3d 971, 973 (7th Cir. 2018) (internal quotation marks omitted).

A. Major adverse cardiovascular event (MACE) warning

1. Qualifications

Actavis moves to exclude Dr. Sharlin's opinion that "[b]ased on clinical trials, [FAERS] reports, and research studies conducted by others, Actavis should have warned about major adverse cardiovascular events (MACE) associated with Androderm by 2011." Actavis Mem. in Supp. of Mot. to Exclude (Actavis Br.) [128] at 2 (citing Mot. to Exclude, Ex. 1 (Sharlin Dep.) [129-1] at 147:15-23, 148:5-16). Actavis argues that Dr. Sharlin is not qualified to offer this opinion because he "is not an expert in epidemiology, pharmacology, or medicine"; "has no experience with [TRT] drugs or the condition or treatment of hypogonadism"; and repeatedly insisted during his deposition that he is offering opinions only on "regulatory compliance." Actavis Br. at 1. Without this professional experience, Actavis contends, Dr. Sharlin cannot properly "evaluate

available scientific evidence or draw any conclusions from such data" about whether there is reasonable evidence of a causal association between adverse CV events and Androderm use. *Id*. at 3-4.

Actavis is incorrect to fault Dr. Sharlin for his lack of experience in epidemiology, pharmacology, and, medicine. In this MDL, the Court has ruled that an FDA regulatory expert can rely on a causation expert's scientific opinions to reach conclusions about what a pharmaceutical company should have done when confronted with scientific evidence. *See, e.g.*, *In re Testosterone Replacement Therapy Prods. Liab. Litig. Coordinated Pretrial Proceedings*, No. 14 C 1748, 2017 WL 1836443, at *14 (N.D. Ill. May 8, 2017) (CMO 48) (determining that it was appropriate for FDA regulatory expert, Dr. David Kessler, "to rely on the testimony of plaintiffs' causation experts regarding what the studies showed and the risks posed by TRT" in offering his opinion "that studies linking TRT to certain increased health risks should have led AbbVie [to] conduct further investigation regarding the link"). Actavis completely ignores this ruling. Although Dr. Sharlin is not an epidemiologist or a medical doctor, he can rely on causation experts' opinions about what scientific studies show to offer separate opinions, based on his regulatory expertise, about whether and when Actavis should have added a CV risk warning to the Androderm label. This ruling is not inconsistent with *Kruszka v. Novartis Pharmaceuticals Corp.*, 28 F. Supp. 3d 920 (D. Minn. 2013), cited by Actavis, where the court determined that an FDA regulatory expert was not qualified to independently opine on "medical causation." *Id.* at 934-35. That said, Dr. Sharlin may not testify at trial that the association between TRT use and CV risk is a "biological fact," Sharlin Dep. at 120:6-21, because he lacks the qualifications to do so.

Next, Actavis emphasizes that Dr. Sharlin conceded during his deposition that he "has never worked for any pharmaceutical manufacturer to determine whether a drug safety signal exists or to analyze a signal to determine whether it necessitated labeling action." Actavis Br. at 4 n.4 (citing Sharlin Dep. at 42:2-43:23). Likewise, Dr. Sharlin admitted during his deposition that he has not counseled a client about whether it should unilaterally change a warning section of a prescription drug label that the FDA has already approved. *See* Sharlin Dep. at 79:16-81:3. According to Actavis, these shortcomings disqualify Dr. Sharlin from opining on whether it was required to make a unilateral change to the warnings and precautions section of the Androderm label.

The Court is not persuaded. Dr. Sharlin might lack the precise credentials Actavis lists, but his regulatory expertise permits him to answer the "specific question" at issue: whether Actavis should have warned about CV risks associated with Androderm by 2011. *Gayton*, 593 F.3d at 617. Dr. Sharlin's expert report shows that he has spent decades reviewing, interpreting, and counseling on a wide range of FDA regulations. *See, e.g.*, Sharlin Report ¶ 7 (stating that for 20 years, Dr. Sharlin has consulted for FDA-regulated companies "on all aspects of regulatory compliance regarding clinical trials, including study design, trial execution, data collection, statistical analysis, interpretation of results, and preparing drug and device submissions for FDA review"); *id.* ¶ 14 (stating that for 15 years, Dr. Sharlin has trained "tens of thousands of employees from hundreds of FDA-regulated companies on a wide range of technical and regulatory topics, including regulatory compliance, drug labeling and drug safety reporting"). Moreover, according to Dr. Sharlin's curriculum vitae, he has evaluated whether warning labels for specific prescription drugs meet FDA standards. *See, e.g.*,

Martin Opp. to Mot. to Exclude (Martin Opp.), Ex. 3 [144-3] at 4 ¶ 8 (stating that Dr. Sharlin has written "a report explaining why the Warning Section in the label for a generic version of [the drug] sulindac was deficient"); *id.* at 4 ¶ 18 (stating that for "a schizophrenia drug," Dr. Sharlin has "analyze[d] the growing body of scientific literature . . . and determine[d] if the company's updates to the drug label's safety information were FDA compliant"). Dr. Sharlin also testified during his deposition that he conducts audits to review pharmaceutical companies' "execution of their pharmacovigilance practices." Sharlin Dep. at 42:18-23. The Court has no difficulty concluding that Dr. Sharlin may draw on this experience to offer opinions about Actavis's unilateral labeling obligations at different points in time.

The Court's ruling in *Smith v. I-Flow Corp.*, No. 09 C 3908, 2011 WL 1750895 (N.D. Ill. May 5, 2011), supports, rather than undermines, this conclusion. *See* Actavis Br. at 4. In *I-Flow*, this Court determined that an expert who was neither a medical doctor nor a medical researcher was not qualified to "render an expert opinion on what the medical literature and research showed at the relevant time." 2011 WL 1750895, at *2. The Court concluded, however, that the same expert could properly testify about the adequacy of the warnings on the medical device at issue. *Id.* Here, as in *I-Flow*, Dr. Sharlin is qualified to offer the failure-to-warn opinion discussed in this section.[1]

2. Fit

Next, Actavis contends that Dr. Sharlin fails to build a logical bridge between the evidence and his opinion that Actavis should have added a CV risk warning to the

[1] The Court does not address all of Actavis's cited cases because (1) they stand for boilerplate legal principles that the Court has already discussed or (2) Actavis cites them without any discussion of their facts.

Androderm label by 2011. According to Actavis, Dr. Sharlin relies heavily on the excluded FAERS data, and the remaining evidence he cites is insufficient. Regarding the first point, the Court reaffirms that its February 14, 2020 order precludes Dr. Sharlin from relying on the excluded FAERS data for his failure-to-warn opinion. Martin's argument to the contrary disregards that order. *See* Martin Opp. [144] at 5 n.2. Actavis's criticism of Dr. Sharlin's other cited evidence, however, rehashes arguments the Court has already rejected.

For example, Actavis criticizes Dr. Sharlin's reliance on the 2010 Basaria study because the FDA stated in 2014 that it had "significant limitations" that "precluded a definitive assessment of the role of TRT" in causing adverse CV events. Actavis Br. at 6; Mot. to Exclude, Ex. 5 [129-5] at 6. Similarly, Actavis argues that it cannot be faulted for failing to analyze post-marketing reports of adverse CV events accompanying TRT use because the FDA made statements as late as 2014 indicating that is not possible to draw conclusions from those reports about casual association. *See* Actavis Br. at 6. But as the Court has explained at length, "'the fact that the FDA was not affirmatively convinced of a causal link between' TRT use and cardiovascular risk 'would not necessarily preclude [a drug manufacturer] from adding the warning on its own.'" CMO 166, 430 F. Supp. 3d at 530-31 (quoting *In re Testosterone Replacement Therapy Prods. Liab. Litig. Coordinated Pretrial Proceedings*, No. 14 C 1748, MDL No. 2545, 2017 WL 1836435, at *9 (N.D. Ill. May 8, 2017) (CMO 47)). The FDA's statements about the Basaria study and post-marketing adverse event reports do not show an analytical gap between Dr. Sharlin's failure-to-warn opinion and the evidence on record.

Nor does Dr. Sharlin's agreement during his deposition that as of the May 2015

FDA-mandated label change, "the epidemiological studies and randomized controlled trials had been inconclusive for determining whether there was a cardiovascular risk associated with testosterone replacement therapy products." Actavis Br. at 6 (quoting Sharlin Dep. at 173:15-174:12). As Martin points out and as the Court has previously explained, "a causal relationship need not have been definitely established" in order for Actavis to have unilaterally added or strengthened a warning through the changes-being-effected process. CMO 166, 430 F. Supp. 3d at 530 (quoting 21 C.F.R. § 314.70(c)(6)(iii)(A); 21 C.F.R. § 201.57(c)(6)(i)); *see* Martin Opp. at 7. Relatedly, the May 2015 FDA-mandated warning label itself references the "inconclusive" nature of the studies, even as it acknowledges that some studies *have* reported an increased CV risk associated with TRT use. CMO 166, 430 F. Supp. 3d at 530. Basaria is one of the studies that has reported an increased risk. *See* Sharlin Report ¶ 54. Dr. Sharlin's deposition testimony that scientific studies have been inconclusive on the issue of risk association affect the weight, not the admissibility, of his failure-to-warn opinion.[2]

Martin's statement that the Basaria study "was neither designed nor powered to detect cardiovascular harm" also fails to raise concerns about the fit between Dr. Sharlin's failure-to-warn opinion and the evidence. Martin Opp. at 6; *see* Actavis Reply [147] at 12. One of Martin's general causation experts has explained that although

[2] In a variation on its arguments concerning the "inconclusive" nature of the scientific studies, Actavis states (without support) that "the MACE language FDA required in February 2015 did not meet the criteria for a pharmaceutical company to unilaterally change that section." Actavis Br. at 6. Again, the Court has explained at length why the FDA-mandated warning language does not necessarily signify that it would have rejected a unilateral attempt by Actavis to add a CV risk warning. *See* CMO 166, 430 F. Supp. 3d at 530-31. Actavis's attempt to renew its unsuccessful argument here does not support exclusion of Dr. Sharlin's failure-to-warn opinion.

Basaria was underpowered, it produced a "significant finding of the positive association between" TRT and MACE, considering that "the effect size is sufficiently large" and the risk of a false positive is low. Martin Opp. to Actavis May 2018 *Daubert* Mot., Ex. 2 [67-1] at 7. Dr. Sharlin's choice to rely on the Basaria study despite its design might affect the weight of his opinion, but it does not warrant exclusion.

Finally, the range of sources on which Dr. Sharlin bases his failure-to-warn opinion supports the Court's conclusion that fit is not a concern. As Martin emphasizes, Dr. Sharlin relies not only on epidemiological studies and randomized controlled trials, but also on the following evidence: documentation from a 2005 meeting in which the FDA told Actavis that it was planning to strengthen the CV risk warning for all TRT drugs; suggestions by Actavis's own marketing team in 2011 to "address the rising [CV] concern head-on by saying Androderm was the least likely form of TRT to cause a heart attack"; and Actavis's decision to exclude men with preexisting CV risks from its pre-market clinical trials. Martin Opp. at 6-7. Regarding this last form of evidence, Dr. Sharlin agreed during his deposition that the pre-market clinical trials themselves did not provide "enough information to discuss cardiovascular risk in the label." Actavis Br. at 5 (quoting Sharlin Dep. at 189:24-190:2). But because Dr. Sharlin's reliance on the pre-market trials focuses on Actavis's decision to exclude a population that might have supplied that information, his deposition testimony does not persuade the Court that there is an analytical gap between the evidence and the failure-to-warn opinion.

For the foregoing reasons, Dr. Sharlin's opinion that Actavis should have added a CV risk warning to Androderm's label by 2011 is admissible. The Court pauses to note that in reaching this conclusion, it did not credit Martin's argument that Actavis could

somehow have accessed the pre-2011 data underlying the Xu, Vigen, and Finkle studies and analyzed it using the authors' methods. *See* Martin Opp. at 3. Although Dr. Sharlin recognizes in his report that Xu, Vigen, and Finkle relied in part on pre-2011 data, *see* Sharlin Report ¶ 2 (table), he does not offer the theory that Martin advances in his opposition brief—which is conjectural.

B. Off-label marketing

Actavis also asks the Court to exclude Dr. Sharlin's opinion that it marketed Androderm for the treatment of age-related hypogonadism, an off-label use. *See* Actavis Reply at 14-15. According to Actavis, Dr. Sharlin is not qualified to offer this opinion because he "has never reviewed a drug manufacturer's post-approval marketing material" for FDA compliance or interacted with personnel from the FDA's marketing divisions. *Id.* at 15 (citing, *e.g.*, Sharlin Dep. at 33:8-12, 258:17-25). This argument is unpersuasive because, as discussed above, Dr. Sharlin has spent decades interpreting, auditing, and applying FDA regulations. In addition, he has developed indications and usage sections for drug labels and taught courses about FDA actions affecting Internet marketing. *See* Sharlin Dep. at 281:2-6; Martin Opp., Ex. 5 [144-5] at 8 ¶ 28. Dr. Sharlin can use this experience to understand and apply the relevant FDA marketing regulations in this case.

Actavis also maintains that Dr. Sharlin's opinion about alleged off-label marketing does not fit the facts of the case because there is no evidence that Martin or his prescribing physician, Dr. Firestone, ever saw Androderm marketing materials. *See* Actavis Reply at 14 (citing CMO 166, 430 F. Supp. 3d at 544 (acknowledging Martin's failure to dispute this gap in the record but noting Martin's deposition testimony that he

saw television ads for TRT drugs generally)). For the same reason, Actavis contends that the probative value of Dr. Sharlin's off-label marketing opinion is substantially outweighed by the risk of unfair prejudice.

Actavis makes no attempt to reconcile these arguments with the Court's prior rulings in this MDL about the admissibility of off-label evidence. At the motion-in-limine stage in several cases, the Court determined that off-label evidence was admissible in similar circumstances because "even if a manufacturer's marketing material played no direct role in causing a plaintiff to take a TRT drug, the material may still be relevant on the question of [the manufacturer's] knowledge that its marketing was misleading or its intent to create an off-label market." *In re Testosterone Replacement Therapy Prods. Liab. Litig. Coordinated Pretrial Proceedings*, No. 14 C 1748, MDL No. 2545, 2017 WL 5029601, at *2 (N.D. Ill. Nov. 3, 2017) (CMO 77) (internal quotation marks omitted); *see also, e.g.*, Order on Remaining Motions in Limine and Modification of Trial Time Allocation, *Rowley v. AbbVie, Inc.*, No. 15 C 2760, MDL No. 2545, Dkt. 73 at 3 (stating that the lack of evidence that marketing materials influenced a prescribing decision would not by itself justify exclusion of evidence concerning off-label promotion). Here, Actavis's intent to create an off-label market is relevant to several claims, including design defect, and to Martin's request for punitive damages. Accordingly, Dr. Sharlin's opinion concerning off-label marketing fits the facts of the case and is not unduly prejudicial. The Court will allow him to offer the opinion, but as in previous bellwether trials, the Court might limit the amount of off-label evidence presented due to concerns about cumulativeness and unfair prejudice. *See, e.g.*, CMO 77, 2017 WL 5029601, at *2.

C. Failure to test

In opposing Martin's argument that it should have accessed and analyzed the pre-2011 data underlying the Xu, Finkle, and Vigen studies, Actavis contends that Martin "abandoned" any failure-to-test theory by acknowledging at the summary judgment stage that "Minnesota tort law does not recognize a duty to study independent of a duty to warn." Actavis Reply at 5-6 (citing *Huggins v. Stryker Corp.*, 932 F. Supp. 2d 972, 987 & n.15 (D. Minn. 2013)). The Court has already disposed of the Xu, Finkle, and Vigen argument just referenced, but it understands Actavis to be arguing that Dr. Sharlin cannot offer *any* failure-to-test opinion. The Court disagrees. Actavis is correct that "[f]ailure to test is not an independent cause of action under Minnesota law," *Huggins*, 932 F. Supp. 2d at 987, but it is equally true that failure to test can be relevant to a negligence claim. *See id.* ("[M]anufacturers' 'duty to test their products . . . to discover defects or dangers associated with use of the products . . . is a subpart of duties to design a product non-negligently, manufacture a product non-negligently, and provide adequate warnings of dangers associated with its use.'" (quoting *Kociemba v. G.D. Searle & Co.*, 707 F. Supp. 1517, 1527-28 (D. Minn. 1989))). Because Martin asserts claims for negligence, design defect, and failure to warn, Dr. Sharlin's opinions about Actavis's alleged failure to investigate CV risk associated with TRT use are relevant, and the Court denies Actavis's motion to exclude them. The Court reiterates that in offering the opinions, Dr. Sharlin cannot rely on the stricken FAERS data. Likewise, he cannot speculate that Actavis could have conducted the same studies as Xu, Finkle, and Vigen using the pre-2011 data therein.

D. Opinions about the FDA's intent and resources

Actavis moves to exclude Dr. Sharlin's opinion that its alleged failure to warn delayed "what [he] characterizes as FDA's conclusion causally connecting testosterone replacement drugs with cardiovascular events." Actavis Br. at 2; *see also id.* (moving to exclude the related opinion that the "FDA otherwise could have identified the risk earlier and initiated a labeling change before March 2015"). Similarly, Actavis argues that the Court should bar Dr. Sharlin from opining about (1) the FDA's intent in denying the 2014 Public Citizen petition, which asked the FDA to issue a warning that TRT increases the risk of CV injury, and (2) what an FDA epidemiologist "meant" to say during testimony at a 2014 meeting about TRT and CV risk. *Id.* at 14.

The Court grants Actavis's motion to exclude these opinions. Dr. Sharlin lacks any basis to offer testimony about what the FDA thought, why it acted, or why it did not act. *See, e.g.*, CMO 48, 2017 WL 1836443, at *16 (ruling that Dr. Pence "lack[ed] a sufficient basis" to testify "regarding the FDA's reasons for acting or failing to act, specifically, her opinion that the FDA did not issue AbbVie a warning for its off-label promotion of AndroGel because the FDA 'lacked the resources to enforce its own rules'"); *id.* (observing that Dr. Pence's opinion "would be inadmissible in any event, either as speculative, unhelpful to the jury, or unfairly prejudicial under Rule 403"); *see also In re Testosterone Replacement Therapy Prods. Liab. Litig. Coordinated Pretrial Proceedings*, No. 14 C 1748, MDL No. 2545, 2017 WL 4772759, at *9 (N.D. Ill. Oct. 23, 2017) (CMO 76) ("Dr Pence . . . is prohibited from speculating about why the FDA acted or failed to act.").

Actavis also moves to exclude Dr. Sharlin's opinions that the FDA is "'too busy' to

analyze FAERS data on TRT products" and "too under-resourced to review promotional materials submitted to it." Actavis Br. at 15 (citing Dr. Sharlin Dep. at 197:7-13, 259:21-260:4). These opinions do not concern the FDA's intent, and the Court has allowed other expert witnesses to offer similar opinions in this MDL. *See, e.g.*, Mar. 12, 2018 Trial Tr., *Mitchell v. AbbVie, Inc.*, No. 14 C 9178, MDL. No. 2545, at 964:8-22 (testimony by Dr. Kessler that the FDA did not have enough personnel to review all "branded ads and other direct-to-consumer marketing"); Mar. 16, 2018 Trial Tr., *Mitchell v. AbbVie, Inc.*, No. 14 C 9178, MDL. No. 2545, at 1921:13-1922:23 (testimony by Dr. Pence that according to a 2007 Institute of Medicine report, there was "widespread agreement" that the FDA's "resources for post-marketing drug safety work are especially inadequate"). Actavis argues, however, that Dr. Sharlin lacks any factual basis to support them. Martin cites only one source in response: Dr. Sharlin's own deposition testimony, which offers no foundation for these opinions. *See* Dr. Sharlin Dep. at 197:2-13 (testifying without further explanation that the FDA is "too busy approving drugs and chasing down off-label use to worry about" interpreting safety data for every TRT drug on the market); *id.* at 260:3-7 ("I would suspect or hypothesize that [the FDA's Office of Prescription Drug Promotion] [is] under-resourced" because the "FDA is under-resourced. Everyone in the FDA is under-resourced"); Martin Opp. at 15 (citing same). Given the lack of any citation to an appropriate foundation, the Court excludes this testimony by Dr. Sharlin.

E. Opinions about Dr. Firestone's prescribing decisions and Martin's intent

Actavis moves to exclude Dr. Sharlin's opinion that "[w]ith different information about the risk of MACE with Androderm, Dr. Firestone would have prescribed Mr. Martin a safer alternative drug or no drug at all." Actavis Br. at 2 (citing Sharlin Report ¶ 4;

Sharlin Dep. at 156:13-157:1). Martin responds that Actavis mischaracterizes Dr. Sharlin's opinion, which states only that Dr. Firestone *could* have made a different prescribing decision had he been adequately warned. *See* Martin Opp. at 9. In fact, Dr. Sharlin offers both opinions (*see* Sharlin Report ¶¶ 4, 41), and the Court concludes that he is unqualified to offer either. Because Dr. Sharlin is not a physician, he cannot weigh in on whether a safer alternative drug was available to treat Martin's condition, nor can he state that prescribing "no drug at all" would or could have been a medically viable option. Illustrating this point, Dr. Sharlin testified during his deposition that he is "not sure what the diagnosis of [Martin's] physician was." Sharlin Dep. at 239:24-240:2.

Even without this, Dr. Sharlin's statement that Dr. Firestone *would* have made a different prescribing decision had the warning been adequate is improper because it concerns Dr. Firestone's intent, which jurors can evaluate without assistance from an expert. *See, e.g.*, CMO 48, 2017 WL 1836443, at *13 ("'[T]estimony regarding intent'" is unlikely to help a trier of fact "because the expert merely draws 'inferences from the evidence' that the jury could draw equally well" (quoting *Dahlin v. Evangelical Child & Family Agency*, No. 01 C 1182, 2002 WL 31834881, at *3 (N.D. Ill. Dec. 18, 2002))). At one point during his deposition, Dr. Sharlin even admitted that he does not "know [Dr. Firestone's] intent" in prescribing Androderm to Martin. Sharlin Dep. at 62:1-6. The Court grants Martin's motion to exclude Dr. Sharlin's opinions about the prescription decision Dr. Firestone would or could have made based on different warning information. For substantially the same reasons, the Court excludes Dr. Sharlin's opinion that Dr. Firestone prescribed Androderm to Martin for an off-label purpose, and that Martin sought treatment from Dr. Firestone "because of his fatigue and decreased

libido," not to "bump up his testosterone levels." Sharlin Dep. at 241:12-25; *see* Actavis Br. at 8, 11 n.8 (moving to exclude these opinions).

Notably, Dr. Pence did not offer any of the opinions discussed in this section, and they are not based on new information. Thus beyond what the Court has already stated, Martin's choice to disclose them for the first time through Dr. Sharlin is not substantially justified. Federal Rule of Civil Procedure 37(c)(1) therefore supplies an additional ground for their exclusion.

Conclusion

For the foregoing reasons, the Court grants in part and denies in part Actavis's Motion to Exclude the Testimony of Plaintiff's Expert Joshua Sharlin, Ph.D. [dkt. no. 127]. Specifically, the Court denies Actavis's motion to exclude the following opinions: (1) Actavis should have warned about CV risk associated with Androderm by 2011; (2) Actavis marketed Androderm for the treatment of age-related hypogonadism, an off-label use; and (3) Actavis failed to investigate CV risk associated with TRT use. The Court grants Actavis's motion in all other respects.

MATTHEW F. KENNELLY
United States District Judge

Date: August 2, 2020